

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

_____	)	
In the Matter of	)	
	)	
ECUMED HEALTH GROUP	)	ADMINISTRATIVE COMPLAINT
a corporation,	)	<u>FOR CIVIL MONEY PENALTY</u>
	)	
and	)	
	)	
AMADOR REYES,	)	FDA Docket: 2004H-0322
JUAN C. CARRAI,	)	
RICHARD W. STONE, M.D., and	)	
ERLINDA E. ENRIQUEZ, M.D.,	)	
individuals.	)	
_____	)	

COMPLAINANT'S MOTION FOR A PROTECTIVE ORDER

Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration (FDA), seeks to preserve its objections to "Defendant Juan C. Carrai's Request For Production Of Documents" (hereafter, "the Carrai Document Request") and "Defendants' Ecumed Health Group And Amador Reyes Request For Production Of Documents" (hereafter, "the Ecumed/Reyes Document Request") by filing, pursuant to 21 C.F.R. §§ 17.23(d) and 17.28, this Motion for a Protective Order.<sup>1</sup> Complainant seeks an opportunity to resolve its

<sup>1</sup> Pursuant to 21 C.F.R. § 17.23(d)(1), a party objecting to a discovery request for production of documents may move for a protective order within ten days of service of the request. The Carrai Document Request was received via facsimile on February 15, 2005, and the Ecumed/Reyes Document Request was received via facsimile on February 22, 2005. Complainant, therefore, must file a motion for a protective order by February 25, 2005, for

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objections with the appropriate counsel for each Respondent. Accordingly, Complainant does not perceive the need for the Presiding Officer to rule on this Motion unless and until, and only to the extent that, the parties are unable to resolve Complainant's objections.

Complainant expressly reserves the right to object to further discovery into the subject matter of these requests and the right to object to the introduction into evidence of any documents produced in response to these requests.

#### Objections to the Carrai Document Request

1. All documents and/or electronic data supporting your contention that Carrai conducted mammography examinations between December 9, 2001 and May 5, 2003.

OBJECTION: Complainant objects to this request to the extent that it seeks documents that are protected by the personal privacy privilege.

2. All documents and/or electronic data supporting your contention that penalties in the sum of \$1,211,000.00 should be imposed against Carrai.

OBJECTION: Complainant objects to this request to the extent that it seeks documents that are protected by the

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the Carrai Document Request and by March 4, 2005, for the Ecumed/Reyes Document Request. See 21 C.F.R. § 17.30(a). Although Complainant is diligently determining which responsive documents exist and are subject to production, it does not anticipate being able to resolve all of its objections by either deadline for filing a protective order. Therefore, Complainant is filing this Motion to preserve its objections for later resolution by the Presiding Officer, if necessary.

attorney-client privilege, the work product doctrine, the personal privacy privilege, and the deliberative process privilege.

Objections to the Ecumed/Reyes Document Request

1. All documents and data supporting your contention that any of the Defendants conducted mammography examinations between December 9, 2001 and May 5, 2003.

OBJECTION: Complainant objects to this request to the extent that it seeks documents that are protected by the personal privacy privilege.

Dated: February 25, 2005

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Michael N. Varrone", written over a horizontal line.

MICHAEL N. VARRONE  
Attorney for Complainant  
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(301) 827-7144

CERTIFICATE OF SERVICE


I certify under the penalty of perjury that on this 25th day of February, 2005, I served a copy of Complainant's Motion For A Protective Order via regular United States mail on the following:

Mario R. Delgado  
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